[redacted]

Assessment of the Consequences of the Design Changes Associated with the Evolution of Bard Inferior Vena Cava Filters, Encompassing the G2 Express, Eclipse, Meridian and Denali Models

Robert M. McMeeking PhD, NAE, FREng, FRSE, LFASME

1. Credentials

This report has been prepared by Dr. Robert M. McMeeking, Tony Evans Professor of Structural Materials and Distinguished Professor of Mechanical Engineering at the University of California, Santa Barbara (UCSB). Over a period exceeding 45 years I have performed extensive research into problems of mechanical failure in a wide range of structural components, including biomedical implants. Among a broad set of skills, our particular expertise in this case focuses on the analysis of mechanical, structural and materials behavior and their implications for fracture, fatigue, tissue penetration and implant stability.

I am a member of the US National Academy of Engineering (NAE) and a Fellow of both the UK Royal Academy of Engineering (FREng) and the Royal Society of Edinburgh (FRSE). These 3 bodies elect their members to recognize their high engineering, scientific and academic accomplishments and the excellence of their contributions, and each body is extremely selective, allowing membership to only a small fraction of those participating in engineering, science and academic pursuits. I am a Life Fellow of the American Society of Mechanical Engineers (LFASME), a status accorded to only senior members with high achievements in mechanical engineering. I served a full ten-year term as Editor of the American Society of Mechanical Engineers Journal of Applied Mechanics, finishing in 2012. The American Society of Mechanical Engineers (ASME) is the leading US professional society concerned with mechanical analysis and the Journal of Applied Mechanics is its leading professional publication addressing the mechanical behavior of solids. I have testified both formally and informally on several occasions to the US Food and Drug Administration (FDA) on issues pertaining to the *in vivo* loading, stress/strain analysis, fatigue, fracture, stability and durability of medical implants. I have served as a consultant for numerous leading companies, providing analyses and expert opinion on the design and reliability of a broad range of devices including heart valves, stents and other biomedical implants. My consulting activities include advising companies on the functionality, design and manufacturing of components including life-critical biomedical implants such as prosthetic heart valves.

I teach mechanical engineering and materials science and engineering to both undergraduate and graduate students at a leading US research university, and I have a part-time professorial appointment teaching and mentoring engineering students at a prominent research university in the UK. My teaching and mentoring activities include providing classes in mechanical engineering design and analysis to equip students with the knowledge and understanding required to carry out the processes necessary to conceptualize, design, analyze and manufacture engineering products. This educational activity encompasses the teaching of ethical and professional responsibilities incumbent on an engineer working to develop components that must be safe, reliable and effective. I have been engaged in teaching in engineering for over 40 years.

My current *curriculum vitae* is included as an appendix.

My billing rate is $400 per hour for consulting work and $800 per hour for deposition and court testimony. My prior testimony in the past 4 years is listed in an appendix. My opinions in this report are to a reasonable degree of scientific certainty.

2. <u>Methodology</u>

I have used my engineering and scientific knowledge of design and analysis of engineering components to both analyze and assess the various models of Bard Inferior Vena Cava (IVC) filters. The quantitative methods I have utilized range from those carried out analytically by geometric, algebraic and calculus methodologies with numerical computation to computer techniques that involve extensive calculations. All of the techniques that I have used are those that I teach in the various classes that I conduct, and I also use all of these techniques in my consulting work for various companies including medical implant manufacturers. All of these methods are informed by engineering drawings of Bard IVC filters and by information regarding the properties of the materials of which they are composed. I also utilize data on *in vivo* conditions that the filters experience after implantation. Some of those data is provided in Bard documentation, while other data are found in medical documents, either books or scientific papers. I also draw on my knowledge and experience derived from consulting, doing research and writing papers on biomedical, bioengineering and biomechanics subjects as a basis for carrying out my assessments of the various Bard IVC filters. In addition, in making my assessments I utilize knowledge, insights and understanding that I have gained during my interactions with the FDA on behalf of medical implant companies.

All of the methods, knowledge and experience that I exercise in making my assessments of the various Bard IVC filters are resources that should be present in a team working in a company to develop biomedical implant devices. Some of the methods and knowledge is quite elementary and will have been mastered by a 3rd year university student in a mechanical engineering program in any institution with an accredited curriculum in that subject. Other methods and knowledge of a more advanced nature that I utilize in making my assessments are such that a student with a masters or doctoral degree specializing in mechanical engineering design and/or analysis, or an engineer with a bachelor's degree who has undergone some experience in mechanical engineering design and analysis or in biomedical implant design and analysis, will have gained them.

The design, analysis and reliability assessments conducted by me for this report and for previous reports I have provided in litigation concerning Bard IVC filters is typical of those routinely conducted during the design validation and verification of engineering devices and components. I have previously investigated the Bard Recovery and Bard G2 IVC filter models and provided reports on their safety, reliability and durability. For my assessments of Eclipse, Meridian and Denali models documented in the current report I have drawn on knowledge I have gained investigating the Recovery and G2 models.

3. Objective Industry and Engineering Standards for Design, Design Control and Analysis

I first summarize standards that apply to all engineering companies, industries and engineers, including those engaged in the business of conceptualizing, designing, manufacturing and marketing medical implant devices. Thereafter, I discuss those standards that, in addition to those applying to all engineering activities, have been developed and have emerged specifically for the medical implants sector of engineering.

3.1 **Engineering standards**

An engineer, and the company or entity that employs the engineer, engaged in the conceptualization, design, analysis and manufacture of a device having implications for the safety and well-being of the person who ultimately uses it are required to act in conformity with objective standards governing engineering activities, where those standards are the ones prevailing in the engineering profession, the engineering industry and the business sector in which the engineer is engaged. The relevant activities are any associated with the performance of engineering duties, and include those contributing to the conceptualization, design, design control, analysis and manufacture of the device. Such standards are identified by authoritative textbooks such as Dieter and Schmidt [1], the professional engineering societies such as the American Society of Mechanical Engineers [2], organizations setting technical standards by consensus such as ASME [3], the International Organization for Standardization (ISO) [4], and the International Medical Device Regulators Forum (IMDRF) [5] (formerly known as the Global Harmonization Task Force (GHTF)), and government regulations such as those promulgated by the FDA under the Federal Food, Drug and Cosmetic Act (FDCA). Some of these standards are ethical [1,2], some are rules accepted by the engineering profession and industry as those required for a minimally satisfactory design [3,4], and some are regulatory, mandated by government agencies such as the FDA. While ethical standards [1,2] differ in nature and standing from the other types of standards, they serve to inform engineers, their supervisors and their employers that there are general and specific responsibilities that must be respected when engineering is carried out, such as those listed by Dieter and Schmidt [1], including valuing the virtues of honesty, knowledge, diligence, the protection of public safety, and the promotion of the welfare of the population. Ethical standards also require an engineer to take responsibility for and carry out a step in an engineering process only if that engineer has the knowledge and experience to undertake the task involved [1,2].

Furthermore, all who are educated in an accredited university bachelor's degree engineering program in the US are given an introduction to ethics and the related responsibilities of engineers and their employers. In that regard, Dieter and Schmidt [1] give a summary of their assessment of how an engineer and the engineer's employer should exercise proper care to avoid transgressing ethical, professional and legal boundaries in carrying out design work. Their list includes the following (numbered according to Dieter's and Schmidt's scheme but paraphrasing, truncating and/or omitting some):

1. Take every precaution to assure that there is strict adherence to industry and government standards.
2. All products should be thoroughly tested before release for sale. An attempt should be made to identify the possible ways a product can become unsafe and tests should be devised to evaluate those aspects of the design that are related to how the product can

become unsafe. When failure modes are discovered, the design should be modified to remove the potential cause of failure.

3. The finest quality-control techniques available are of no relevance if the product being marketed is in fact defective. However, quality-engineering methods have an important role in helping to ensure that products are safe and effective.
4. Make a careful study of the relationship between your product and upstream and downstream components. You are required to know how malfunctions upstream or downstream of your product may cause failure to your component. You should warn users of your product of any hazards of foreseeable misuses based on these system relationships.
5. Documentation of the design, testing and quality activities is very important. If there is a need to recall a product, it is necessary to be able to pinpoint products by serial or lot number. The compilation of good, complete records will help establish habits of competent behavior.
6. There should be a formal design review before the component, device or product is released for production.

3.2 Standards specifically applicable to medical implant companies

In a more specific setting relevant to companies producing medical implant devices, companies are expected and required to act in accordance with applicable industry standards, and to adhere to them when choosing how to react to product complaints, adverse events data, and information in the scientific and medical literature. As noted above, such standards include, but are not limited to, those laid down by consensus organizations such as ISO, items promulgated by IMDRF/GHTF, and regulations and guidance put in place by the FDA. In addition, there is an expectation that companies will operate on some standards that may not be formally specified, such as adhering to the use of technology, design and production methods that are at the state of the art, to take actions that will enable the company to become familiar with the state of the art in their areas of engineering activity, and to modify designs and production methods when the company realizes that it has fallen behind the state of the art relevant to its products. A similar standard that is not formally specified is that companies should seek to identify and learn of best practices in all of its engineering activities, and to implement them.

In terms of how the FDA regulates the process by which medical implant devices are brought to market, and authorizes such products, the framework involved includes requirements for quality system management to ensure safety of components and devices. This feature of the responsibility of companies can be understood by reference to FDA regulations set out in the Code of Federal Regulations (CFR) and to standards and guidance provided by organizations such as ISO and IMDRF/GHTF that are considered to be authoritative by the FDA. The wider context is FDA regulation of medical implant companies and the applications such companies make to the FDA to gain authorization, clearance or approval for them to market their products, all handled by the Center for Devices and Radiological Health (CDRH) within the FDA. However, I will focus only on those aspects of that wider context that relate to quality systems requirements in design, design control, analysis and production, but with the understanding that the ensuring of device safety and effectiveness requires the cooperation of the companies, and that FDA requirements are the minimum ones and are but one piece of broader industry standards. Thus a company must strive to achieve industry standards if they go beyond those

laid down by the FDA, and the company cannot accept the status quo if it invokes standards that merely meet those of the FDA but fall short of achieving equivalence with higher standards that currently prevail in its industry. It should also be stated that manufacturers should always err on the side of caution, in terms of ensuring regulatory compliance, compliance with industry standards and safety of its devices.

I note that one of the principal aims of IMDRF/GHTF is to increase access worldwide to safe medical technologies [5], and that the original GHTF study groups had membership having an appropriate balance between industry and regulatory experts [6]. Its documents and guidance were generated by consensus and peer review [7], following a rigorous and stringent set of standardized procedures [8]. As a result the guidance documents that were developed are highly reliable and have the status of industry standards. The principles that I list below were finalized in 2012 [9], but they codify principles that, when applied to the conceptualization, design and analysis of products other than medical implant devices, are identical to those applicable more broadly to the engineering profession and industry. Thus, independent of their history, the date upon which they were first published and their current status within IMDRF, they represent standards that have applied for decades to the medical implant device industry and they are still relevant today.

3.2.1 <u>*GHTF Essential Principles of Safety and Performance*</u>
GHTF generated principles that are aimed at ensuring the safety and performance of medical implant devices, and that are therefore industry standards, with some of them being relevant to the processes of design, design control and design analysis. The essential principles applicable to all medical devices are as follows [9]:

1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; eliminate risks as far as reasonably practicable through inherently safe design and manufacture; reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and inform users of any residual risks.

3. Medical devices should achieve the performance intended by the manufacturer and be

designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5. Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6. All known and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

Relevant essential principles specified by GHTF relate to devices such as IVC filters possibly posing mechanical risk. I cite the only one relevant to IVC filters [9]:

- Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

3.2.2 *FDA Mandated Quality System Regulation and Design Controls*

The 1976 Medical Device Amendment to the FDCA led to the FDA specifying Good Manufacturing Practice (GMP) requirements to achieve consistent manufacturing of medical devices relative to their safety and effectiveness. GMP was further revised in 1996 to include Quality System Regulation (QSR) requiring medical device manufacturers to implement, *inter alia*, quality system requirements and design controls [10]. Under these regulations/standards [11] "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part," and the code specifies management responsibilities and audit requirements to maintain the system [12,13]. Notably, the code specifies a requirement to employ "sufficient personnel with the necessary education, background, training, and experience" to assure implantation of the quality system, and that such human resource infrastructure be maintained [14].

3.2.2.1 *Design Controls*

QSR design control regulations apply to all Class II and Class III devices to ensure that the design and analysis of a medical device is implemented in such a manner that all specified design requirements are achieved [15]. I quote the design control regulations *verbatim* [15]:

(a) *General*. Each manufacturer of any class III or class II device, [and the class I devices listed

in paragraph (a)(2) of this section – omitted], shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(b) *Design and development planning*. Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(c) *Design input*. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) *Design output*. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

(e) *Design review*. Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

(f) *Design verification*. Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

(g) *Design validation*. Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

(h) *Design transfer*. Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

(i) *Design changes*. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval

of design changes before their implementation.
(j) *Design history file.* Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

4. The Bard G2 and G2 Express IVC Filters
The Bard G2 Express IVC Filter (later known as the G2X) is a modification of the Bard G2 IVC Filter with a retrieval hook added to its cap. An engineering drawing of the G2 model is shown in Figure 1 [16], while Figure 2 shows the G2 Express [17]. Otherwise the G2 and the G2 Express are identical, apart from some details of the outside profile of the cap holding the limbs.

4.1 The G2 Filter
I note that the G2 filter has significant problems related to migration, tilt, perforation of the wall of the vena cava, and fracture due to fatigue failure of its limbs. The migration can be movement of the filter as a whole, either cephalic or caudal, though in the case of the G2 the incidences of caudal migration appear to be more common than those of a cephalic nature. Tilt occurs when the axis of the conical profile of the filter is not parallel with the axis of the vena cava, while perforation involves the extremities of the filter moving outside of the wall of the vena cava. Such perforations seem likely to occur by the ends of the limbs first penetrating through the vena cava wall, and by the process continuing due to more and more of the limb's extent pushing through the tissue. In the case of fracture, pieces of the filter break off, usually a segment of a filter limb, and the loose piece then may or may not move to a distal organ such as the heart or lungs. Fracture is caused by fatigue damage to the nitinol associated with cyclic loading caused by repeated changes to the cross-sectional dimensions of the vena cava, or by the impact of successive clots trapped by the filter. It is likely that tilt leads to perforation, while it is also likely that perforation leads to tilt. It is known that both perforation and tilt are associated with a greater likelihood of the filter fracturing. A summary of experience with implanted G2 filters is provided by Parisian [18], where the fore-mentioned problems with the G2 filter are compiled and described. Other considerations, including the observation that it is fatigue damage that leads to the fractures of the G2 filters, are described in the reports of Ritchie [19] and Fasching [20].

In addition, I have addressed the G2 filter from considerations of mechanical engineering and materials engineering and provided my opinions and the results of my analysis in several reports, including one related to the litigation in Fox vs. Bard [21]. My key findings in my investigation of the G2 filter summarized in those reports are as follows:

1. The alternating strain in the arm of a G2 filter without tilt is 0.56%, where the arm has fully perforated a 14 mm diameter vena cava and has been endothelialized by the tissue of the vena cava, and the diameter of the vena cava is expanding and contracting by 1mm.
2. A strain concentration where the arm enters the sheath can elevate the alternating strain well above the level given in 1., in some cases by factors of 10 or more.
3. Such high levels of alternating strain resulting from strain concentrations will cause rapid fatigue fracture of an arm, delayed, however, by the time after implantation required for perforation and endothelialization. The unstable, somewhat unconstrained manner by

which the sheath holds the limbs means that continued perturbation of the vena cava by respiration, valsalva or cough can bring the arms and the sheath into interference, leading to an elevation of the strain concentration that may happen early after implantation, that may be delayed for some time, or that may never happen.

4. A clot that arrives at the filter in the venous blood flow and that is trapped by it can cause very high strains in the legs and feet of the filter due to a water-hammer effect. Such impacts are likely to cause fracture of the feet and legs of the filter, or to cause fatigue damage to occur in them when multiple clots are arrested sequentially.
5. The filter is unstable after implantation in the vena cava and it is very likely that it will always tilt, except in the rarest circumstance in which the arms perfectly align with the wall of the vena cava; even in the latter situation it is likely that the filter is still sufficiently unstable that tilting ensues.

In my further analysis of the G2 filter, some of which has not been summarized in written reports but which I have described in depositions, I have found that perforation contributes to tilting, and tilting contributes to perforation. In addition, I observe that the small diameter of the wire composing the arms and legs of the filter makes it probable that they will penetrate into the tissue of the vena cava, leading them to perforate its wall.

I judge the features of the G2 I have just described to be deficiencies of its design, and this conclusion leads me to deduce that Bard did not adhere to professional and industry standards in the engineering activities involved in the conceptualization, design and analysis of the filter. For example, it is likely that personnel without the knowledge, experience and training needed to design and analyze the filter were involved in the activities. Furthermore, it is probable that the G2 was not thoroughly tested prior to being marketed, and that the attempts to identify all possible failure modes of the filter were inadequate. In addition, the fact that the G2 filter remained on the market even after Bard and its employees became aware of the many failures it was experiencing is contrary to engineering professional, industry and government standards, which require that when failure modes are discovered, the design should be modified to remove the potential cause of failure. In addition, it is clear that Bard did not use design and analysis methods that conformed to the state of the art in its industry at the time the G2 filter was designed, as they would have identified the potential failure modes if proper design and analysis procedures had been carried out. Indeed, as I have pointed out in my reports such as [21], Bard did not even use strain-analytical methods that were within the skill set of an undergraduate engineering student, and that would have shown Bard that the G2 design had potential failure mechanisms that would compromise it after implantation in patients. Furthermore, Bard's actions in designing the G2 filter were contrary to GHTF Essential Principles of Safety and Performance 1 through 4 & 6 as listed above. The company also failed to adhere to the additional bulleted GHTF essential principle stated above relevant to protection of the patient from mechanical risks. As all of these GHTF essential principles are accepted to be authoritative industry standards, this shows that Bard was failing to adhere to the relevant industry standards when it designed the Bard G2 filter. I note that the conceptualization, design, analysis and bench testing of the G2 filter predated the publication of the GHTF essential principles; however, these essential principles enunciated by GHTF codify the industry and professional standards that had prevailed for some time prior to the time when the G2 filter was developed. Therefore, these essential principles represent standards that Bard should have adhered to when it conceptualized,

designed, analyzed and bench tested the G2 filter. I further note that in my reports such as [21] I have extensively described why Bard's design procedures were deficient and how they failed to meet accepted objective standards, and my reports should be consulted to obtain fuller details. In addition, Bard was not frank and honest with the FDA in that the company did not fully inform the FDA of the deficiencies that the G2 filter was exhibiting after implant, and thus Bard was not adhering to professional, industry and government standards; these aspects of Bards activities have been documented by Parisian [18], where further details are to be found.

I make the following further observations of the G2 filter and the conditions *in vivo* that it experiences. In my written reports regarding the G2 filter I used an assumption that during respiration the vena cava diameter expands and contracts by 1 mm as this was the knowledge available at the time of the design of the Bard Recovery filter, the predicate to the G2 model. This assumption was therefore used by Bard in its analysis and testing of the Recovery filter and carried over to the re-design that led to the G2. Recent research has led to the conclusion that respiration typically causes expansion and contraction of the vena cava that is significantly larger than 1 mm. Murphy *et al.* [22] observed that during normal respiration of a supine patient the diameter change could be as large as 1.8 mm for vena cavas that ranged in size from 10.2 mm to 26.7 mm in diameter. For the purpose of being conservative I combine the 1.8 mm diameter change with the smallest diameter of 10.2 mm and infer that the diameter change during normal respiration can be as high as 18%. In a 14 mm diameter vena cava this would lead to a diameter change of just over 2.5 mm, significantly larger than the 1 mm assumed above. The diameter change of 2.5 mm in a 14 mm diameter vena cava leads to alternating strain that can be as high as 1.4%, *i.e.* 2.5 times 0.56%. My previously reported results [21] show that the alternating strain in an arm in a filter implanted in a 20.4 mm diameter vena cava is 0.32% when endothelialization has taken place and the vena cava diameter change is 1 mm. In this case the arm can have perforated the vena cava wall, but that increases the strains only slightly. An 18% diameter change in this case will lead to it being 3.6 mm, resulting in alternating strains equal to 1.15%, *i.e.* 3.6 times 0.32%. In both of these examples fatigue failure by fracture can be expected to ensue relatively rapidly. Data in the literature on fatigue failure of nitinol [23] suggest that a filter arm experiencing alternating strains of 1.38% in a 14 mm diameter vena cava would last between 5,000 and 100,000 breaths, or between 5.5 hours and 111 hours at 15 breaths per minute. Therefore, the filter would lose an arm by fracture in a 14 mm diameter vena cava shortly after the filter becomes completely perforated to the extent possible and then endothelialized. A filter arm endothelialized to the walls of a 20.4 mm diameter vena cava and experiencing alternating strains of 1.15% would fare little better, lasting approximately the same time after completing the process of endothelialization.

In research by Laborda *et al.* [24] published in 2014 it was found that the diameter of the vena cave reduced by 50% during valsalva. In a 14 mm diameter vena cava this would lead to a diameter change of 7 mm, leading to alternating strain that can be as high as 3.92%. A 50% diameter change in a 20.4 mm diameter vena cava will lead to it being 10.2 mm, resulting in alternating strains equal to 3.26%. In both of these examples fatigue failure by fracture can be expected to ensue relatively rapidly, and it is even possible that 1 valsalva maneuver can compromise the filter, either by fracturing it, or by permanent deformation misshaping it and causing it to fail as a clot-trapping device. If it survives long enough, a filter arm experiencing alternating strains of 3.92% in a 14 mm diameter vena cava would last only about 500 valsalva

maneuvers before fracturing by fatigue [23]. Therefore, the filter would lose an arm by fracture shortly after it becomes completely perforated to the extent possible and then endothelialized if the recipient engages in valsalva frequently. A filter arm endothelialized to the walls of a 20.4 mm diameter vena cava and experiencing alternating strains of 3.26% due to valsalva would last approximately 1,000 valsalva maneuvers before fracturing by fatigue. There is also an increased risk that valsalva will cause severe damage to the legs of the filter, leading to fractures or permanent deformation that misshapes the legs, causing the filter to dislodge and migrate cephalically. Furthermore, I note that it is probable that the very large diameter changes experienced during valsalva will cause fatigue failure of the legs of the Bard G2 filter as they will be forced to deflect by very large amounts during that maneuver.

I have testified in deposition that tilt increases the probability of fracture by fatigue failure. A contributing reason is that alternating strains are increased because of the larger span between the points where the filter limbs engage the wall of the vena cava. If a filter is tilted by 45°, this will raise the alternating strains by 40% compared to those in an untilted filter in a given vena cava in identical circumstances. Thus the worst cases from above for respiration lead to alternating strains of 1.98% for a filter in a 14 mm diameter vena cava and to alternating strains of 1.63% for a filter in a 20.4 mm diameter vena cava. Therefore, tilt will reduce fatigue life even further than illustrated above where respiration is causing the fatigue damage. In valsalva tilt will raise the alternating strains to 5.54% in the worst case in a 14 mm diameter vena cava and to 4.61% in the worst case in a 20.4 mm diameter vena cava.

I further note that damage caused by valsalva can compound that due to respiration and together lead to fatigue failure by fracture more rapidly than when valsalva is absent, or when valsalva occurs but the alternating strains from breathing are small enough to cause negligible fatigue damage.

The comments made so far regarding the alternating strains in the G2 filter do not take into account the possibility of a strain concentration where the arms and legs enter the sheath. As noted above, such a strain concentration will increase the magnitudes of the alternating strains, perhaps modestly by 10% or 20% if the concentration factor is not very high, or by multiples of 2 or 10 or higher if the concentration factor is severe. Such an effect will make the fatigue life problem worse.

I have concentrated so far on the worst cases that can be identified for the alternating strains in the arms of the G2 filter. Such worst cases should have been the focus of the design process when the G2 filter was being conceptualized, designed and analyzed. I have seen no evidence that this in fact occurred. For example, the possibility of a strain concentration should have been eliminated, either by breaking, curving or chamfering the edge in question at the mouth of the sheath, or by stabilizing the legs so that they would not interfere with the sheath. A similar comment can be made on the need to eliminate fretting of the limbs with each other, as this can initiate fatigue damage and elevate the alternating strains above the levels I have already identified. The failure to identify the worst cases for fatigue conditions was a failure to adhere to engineering professional, industry and government standards, as noted above.

In addition to the worst cases, it can be concluded that the alternating strains in the arms of some G2 filters implanted in patients experienced alternating strains that would have ranged from negligible magnitudes to those approaching the worst cases I have identified above. Such variation would be due to patient attributes, such as the strength and stiffness of the tissue in the wall of the vena cava influencing the degree of perforation, the tendency for the patient to endothelialize the filter and how strongly and rapidly that occurs, the details of the local shape of the vena cava that influence how tilting occurs, and variations in the treatment of the filter during a normal and successful implantation that would affect the final relative configuration of the filter limbs and cap.

A possibility is that the stiffness of the implanted filter reduces the magnitudes of the alternating strains due to the constraint the filter represents to the motion of the walls of the vena cava as its diameter expands and contracts. Bard has made such an assertion, supported by the accepted view of vena cava dynamics that respiration draws blood up and down the inferior vena cava, causing it to contract at the infrarenal location during inspiration and to expand there during exhaling, with the intrathoracic and abdominal pressures driving the process of vena cava expansion and contraction [22]. This argument asserts that the loading on the vena cava wall at all times is simply a pressure difference across the wall with the contents of the abdomen acting like a fluid loading on the outside of the vena cava. In turn, this model depends on the wall of the vena cava being stiff enough in bending to remain oval under pressure loading and pressure fluctuations, as it is observed to be *in vivo* [22,24]. However, elementary calculations suggest that, given the stiffness and thickness of the vena cava wall, the changes to its diameter caused by pressure fluctuations driven by respiration would be significantly smaller than observed experimentally [22]. I therefore conclude that it is not simply a pressure fluctuation that expands and contracts the vena cava during respiration, but rather the motion of relatively stiff organs adjacent to the vena cava plays a role in forcing it to expand and contract, thereby enabling the change in its diameters and aspect ratio. The diameter changes during respiration would thus be unaffected by the presence of an implanted filter unless the filter is much stiffer than those in the Bard family. Therefore, I conclude that the expansions and contractions of the vena cava that I have identified above are relevant to the conditions experienced by an implanted filter, and that their magnitudes should not be assumed to be reduced due to the presence of the filter when designing and testing a compliant filter to be implanted, nor when assessing the possible conditions that filters have experienced after implantation, as in this document.

A conclusion that can be drawn from the above is that the likelihood of fracture due to fatigue in the Bard G2 filter is patient dependent, and can be influenced by the details of how a normal, successful implantation occurred, with some patients having an experience in which their G2 filter offers no danger of fracture while other patients are not so fortunate. However, it is entirely predictable that some patients will have severe fracture problems with their G2 filter, given the prevalence of tilting, perforation and endothelialization among implanted G2 filters. It is further noted that the alternating strains can be very high, and associated with fatigue lifetimes that are very short.

4.2 The G2 Express Filter

As noted above, the G2 Express filter is the G2 filter with a snare hook added to the top of the cap. There are some detail differences in the shape of the outside profile of the cap, as can be

seen in Figures 2 & 3, where Figure 3 [25] is a detailed drawing of the sheath or cap for the G2 Express. Otherwise, the design of the G2 filter was left unchanged. Of particular significance is the treatment of the edge marked 5 with a triangle around it in Figure 3. The note explaining 5 is that this location is to be masked during bead blasting of the cap. As a consequence, the corner at the inside diameter of the cap mouth is not bead blasted. The purpose of bead blasting, as noted in Figure 3, is to break edges to soften sharp corners. This situation means that the corner at the inside diameter of the cap mouth remains sharp after production. It is the sharpness of this edge that contributes to the possibility of high strain concentrations when the limbs of the filter interfere with the cap, a feature that was described and criticized in my previous reports such as [21]. I conclude therefore that no changes were made that would improve the fatigue life of the filter when the design modification of the G2 to the G2 Express was undertaken. Similarly there are no changes that would influence the tendency for tilt, perforation and migration. Therefore, the bad characteristics of the G2 apply equally to the G2 Express, and the comments above regarding the G2 are relevant to the G2 Express.

As a consequence, I will take the attributes of the G2 as the starting point for my assessment of the design transitions that modified the G2 Express (via the G2 X which is identical to the G2 Express) into the Eclipse, followed by the Meridian and finally to the Denali.

5. The Bard Eclipse IVC Filter

As noted in Bard's 510(k) Premarket Notification for the Eclipse Filter [26], the only change to the filter compared to the predicate G2 Express filter is that the arms and legs of the device are electropolished before filter assembly and annealing, whereas the limbs of the G2 Express are mechanically polished [27]. This fact is confirmed in Bard's 510(k) Submission for the same filter model [28] and in the device description pages in that submission [29]. It should be noted that electropolishing, an electrochemical treatment of the surface of the material that removes some of it, slightly reduces the dimensions of the component subjected to it. However, the wires to be electropolished for assembly into the Eclipse filter are specified to be slightly larger in diameter than those previously used in the G2 family, so that after electropolishing the final diameters are the same. This further confirms that, apart from the condition of the polished surfaces, the Eclipse and the G2 Express filters are mechanically and materially identical.

[redacted]

[redacted]

[redacted]

Because no other attributes of the filter were changed when the G2 Express was redesigned as the Eclipse, design deficiencies represented by tilt, perforation and migration were left unaffected. Therefore, such design deficiencies of the Eclipse will be just as bad as those seen in the G2 family.

Therefore, I expect the only change due to the electropolishing of the limbs of the Eclipse to be a marginal improvement in the incidence of fracture due to fatigue when compared with the G2 filter family. As noted above, Bard's Filter – Fracture Analysis [31] confirms that fracture of the Eclipse filter occurs, and was still taking place in 2016 at a level that was only marginally better than the prior generation devices, which is, as I explain above, confirmation of my opinions regarding the effect of the design changes.

6. The Bard Meridian IVC Filter

The Bard Meridian filter is a re-design of the Bard Eclipse filter with caudal anchors added to the arms. The Meridian filter is described in a Bard V&V plan document dated 24th June 2010 [32], and an illustration of the filter is provided as Figure 4 [33]. As can be seen, there are nib-shaped titanium alloy hooks attached to each arm, with 3 of them at the elbow and 3 of them at the wrist, alternating in position in neighboring arms. The hooks, described as anchors [32], are intended to allow the filter to better resist caudal migration, and the rationale for appending them in differing locations on neighboring arms is so that this benefit can accommodate a broad range of vena cava diameters. I infer from this that the 3 anchors at the wrist are intended to inhibit

caudal migration in larger diameter vena cavas whereas the 3 at the elbow are intended to deal with smaller diameter vessels. The device description [32], which compares the Meridian filter to the predicate Eclipse model, states that "No other design changes have been made to the filter."

Since no design changes, other than the caudal anchors, were made to the Eclipse to re-design it as the Meridian, it follows that in identical circumstances in a given vena cava the Meridian filter will experience identical conditions of strain, stress and loading as is imposed on an Eclipse model. Therefore, if the Meridian reaches the same configurations in a given vena cava (i.e. tilt, perforation, migration) and is subjected to the same phenomena, such as vena cava diameter expansion and contraction due to respiration and valsalva, the trapping of clots, and endothelialization, the Meridian will also suffer the same failures as the Eclipse. Since the Eclipse design is only marginally improved as compared to the G2 family of filters, the failure rate of the Meridian will approach that of the G2 family of filters if the conditions experienced by the Meridian are the same as those experienced by a G2, G2 Express or G2X, and will be identical to that of an Eclipse filter. The question, therefore, is whether the caudal anchors will inhibit the Meridian filter from experiencing the same configurations of tilt, perforation and migration within the vena cava.

The Meridian filter was subjected to a series of bench tests that supposedly demonstrate that the filter was capable of withstanding *in vivo* conditions after implantation. These include respiratory flat plate fatigue [34], diaphragmatic flat plate fatigue [35], caudal migration [36,37] and tilt [38].

[redacted]

[redacted]

[redacted] However, further tilt can be enabled by asymmetric penetration of the limbs into the vena cava wall, and it is probable that tilting generates forces on the vena cava wall that will drive such asymmetric penetration of the limbs. As there is nothing in the design of the Meridian filter that will inhibit perforation of the vena cava wall compared to the Eclipse, I would expect that tilting and perforation in the Meridian filter will occur at rates, to extents and in numbers comparable to those experienced in the Eclipse filter, and therefore comparable to those phenomena in the G2. Furthermore, the Meridian filter will be endothelialized at rates similar to what is experienced in the Eclipse and G2 filters. Since tilt, perforation and endothlialization all enhance the probability of fracture due to fatigue, it is inferred that the fracture rates in the Meridian filter will be similar, if marginally lower, to those in the G2, G2 Express, G2X and similar to that of the Eclipse.

Caudal migration problems may be improved somewhat by the use of the caudal anchors in the Meridian filter. However, improvement on caudal migration is uncertain as it is not known how much resistance is actually required to avoid caudal migration of the entire filter. In this regard the results of the tilt test [38] are notable as the caudal anchors in that test were unable to eliminate the caudal motion that almost certainly occurs during tilt. Therefore it seems likely that there is little improvement, if any, in caudal migration resistance of the Meridian compared to other Bard filters. Just because the Meridian filter performed better than the Eclipse model in a caudal migration bench test does not prove that the Meridian filter would be associated with much improved caudal migration resistance *in vivo*. I note that no changes were made to the Meridian design that would improve cephalic migration resistance. I have demonstrated that tilt, perforation, endothelialization and fracture in the Meridian filter are very likely to be no better than those of the Eclipse model. Fracture is thus very likely to be only marginally improved over the G2 family and the Eclipse, and the other failure modes, other than perhaps caudal migration, will be unchanged.

I note that my assessment indicates that Bard failed to follow best practices, standard industry procedures and adherence to diligence in choosing to add caudal anchors to the arms of the filter without first establishing a root cause for the caudal migration that the G2, G2 Express and Eclipse filters were experiencing. Therefore, this episode represents a violation by Bard of engineering professional and industry standards. In the absence of knowledge of the root cause of the caudal migrations of the G2, G2 Express and Eclipse filters, Bard was unable to select a design change that would actually deal with the majority of caudal migrations the filters were experiencing. The features of the G2, G2 Express and Eclipse filters that I have just described are deficiencies of their designs. These design deficiencies are the result of Bard's failure to adhere to professional and industry standards in the engineering activities involved in the conceptualization, design and analysis of the filter. For example, the attempts to identify all

possible failure modes of the Meridian filter were inadequate, and the Meridian was not thoroughly tested prior to being marketed. In addition, the fact that the Meridian filter was placed on the market despite knowledge by Bard and its employees of the many failures experienced by filters that were almost identical is contrary to engineering professional, industry and government standards, which require design modifications to eliminate potential causes of failures when failure modes are discovered. In addition, it is clear that Bard did not use design and analysis methods that conformed to the state of the art in its industry at the time the Meridian filter was designed. Proper design and analysis methods would have identified the potential failure modes. I have seen no evidence that Bard even used strain-analytical methods that were within the skill set of an undergraduate engineering student, and which would have shown Bard that the Meridian design had potential failure mechanisms that would compromise it after implantation in patients. Furthermore, Bard's conduct in designing the Meridian filter was contrary to GHTF Essential Principles of Safety and Performance 1 through 4 & 6 as listed above. Bard also failed to adhere to the additional bulleted GHTF essential principle stated above relevant to protection of the patient from mechanical risks. As all of these GHTF essential principles are accepted as authoritative industry standards, this shows that Bard was failing to adhere to the relevant industry standards when it designed the Bard Meridian filter. I note that the conceptualization, design, analysis and bench testing of the Meridian filter predated the publication of the GHTF essential principles; however, these essential principles enunciated by GHTF codify the industry and professional standards that had prevailed for some time prior to the time when the Meridian filter was developed. Therefore, these essential principles represent standards that Bard should have adhered to when it conceptualized, designed, analyzed and bench tested the Meridian filter. I note that in my reports such as [21] I have extensively described why Bard's design procedures used for the Recovery and G2 filters were deficient and how they failed to meet accepted objective standards. These same criticisms apply also to the manner in which Bard carried out the design of the Meridian model; my reports should be consulted to obtain more complete details. In addition, Bard was not frank and honest with the FDA in that the company did not fully inform the FDA of the deficiencies that the G2 and Eclipse families of filters were exhibiting after implant which would also affect the re-designed Meridian. Thus Bard was not adhering to professional, industry and government standards; these aspects of Bards activities have been documented by Parisian [18], where further details are to be found.

7. <u>The Bard Denali Filter</u>

At about the same time as the Meridian filter was developed, Bard also conceptualized, designed and tested a new model, the Denali. This filter is made from a tube of nitinol rather than from wires, and the limbs are laser cut out of the tube material with the apex of the filter being a segment of the tube that is uncut. A retrieval hook is attached to the distal end of that segment of uncut tube. In addition, the legs are equipped with cranial anchors to inhibit cephalic migration that are somewhat similar to the hooks at the feet of previous models of Bard filters, and some legs have caudal anchors to inhibit caudal migration. In addition, there is a penetration limiter at the foot of each leg in the form of a small flat segment of metal that is intended to inhibit penetration and perforation of the vena cava wall. The Denali filter is electropolished, but that is done terminally. An engineering drawing of the Denali filter is provided in Figure 5 [41]. The thickness of the limbs of the Denali (*i.e.* the thickness of the nitinol tube from which it is cut) is

almost exactly the same as the thickness of the limbs of the Recovery, G2, G2 Express, G2X, Eclipse and Meridian filters [42].

A feature of the re-design that created the Denali filter is that the use of a unitary tube from which the cap and limbs are cut eliminates the possible severe strain concentration associated with potential interference of the wire legs and the cap, and the possible strain concentration in the weld between limbs, that were both deficiencies of the design of the Recovery, G2, G2 Express, Eclipse and Meridian filters, and which I have discussed in my reports such as [21]. However, the re-design introduced a feature that is very likely to cause a strain concentration upon motion and distortion of the limbs associated with insertion of the filter into its delivery tube, its implantation and due to diameter changes of the vena cava after implantation. This strain concentration can occur where the limbs merge into the tubular cap of the filter, as that feature causes a notch between adjacent limbs, as can be seen in Figure 6 [42]. The strain concentrating effect would be most severe when adjacent limbs are pulled directly away from each other, as may happen in the filter after implantation. In addition, it is highly probable that bending of the limbs directly associated with expansion and contraction of the vena cava will be associated with a strain concentration at the specified location at the apex of limbs. Strain and stress concentrations raise the strain and stress magnitudes present in a component above nominal levels [1], and mechanical and design engineers are expected to pay close attention to strain and stress concentrations as many fatigue fractures occur due to them [1,39]. I see no evidence in the Bard documentation I have read that Bard gave any consideration to the strain concentration what would very likely occur at the apex of the limbs, and that potentially would cause fatigue fracture problems in the Denali model. Such an omission represents a failure to adhere to professional and industry standards as the treatment of strain and stress concentrations is a necessary and standard step in the design, analysis and testing of any component subject to distortions or loads, such as the Denali experiences upon insertion into its delivery tube, its implantation and *in vivo*.

The engineering drawings of the Denali [42] show that, while different in detail, it is quite close in overall shape to the previous Bard filter models. I therefore draw the conclusion that in identical circumstances in a given vena cava the Denali filter will experience similar conditions of strain, stress and loading as is imposed on the G2, G2 Express, Eclipse and Meridian models. Therefore, if the Denali reaches the same configurations in a given vena cava (*i.e.* tilt, perforation, migration) and is subjected to the same phenomena, such as vena cava diameter expansion and contraction due to respiration and valsalva, the trapping of clots, and endothelialization, the Denali will suffer failures similar to those experienced by the previous Bard filter models. The failure rate of the Denali will approach that of the G2 family of filters, the Eclipse and the Meridian if the conditions experienced by the Denali are the same as those experienced by a G2, G2 Express or G2X, Eclipse and Meridian, and may even be higher due to the presence of the strain concentration described above. The question, therefore, is whether its caudal anchors and penetration limiters will inhibit the Denali filter from experiencing the same configurations of tilt, perforation and migration within the vena cava that is associated with the G2, G2 Express, Eclipse and Meridian filters, and that are associated with an increased likelihood of fracture in those filters. Furthermore, Bard, in its design validation and verification procedures, its bench testing and its analysis, did not demonstrate that the Denali would be free of migration and fatigue fracture even in the absence of tilt, perforation and penetration, and

caudal migration. While the Denali was subjected to bench tests, they were, in my assessment, inadequate for testing whether the filter would be free of tilt, penetration, migration and fatigue fracture.

The Denali filter was subjected to a series of bench tests that supposedly demonstrate that the filter is capable of withstanding *in vivo* conditions after implantation. These include respiratory flat plate fatigue [43], diaphragmatic flat plate fatigue [44] and caudal migration [45].

[redacted]

[redacted]

The arms of the Denali filter do not have penetration limiters. As a result, they will penetrate and perforate the vena cava wall in a manner and at a rate that will be similar to that experienced by the previous Bard models of filter such as the G2, the G2 Express, the Eclipse and the Meridian.

In my opinion, the penetration limiters on the legs of the Denali are very small and will have little effect on inhibiting the legs penetrating and perforating the vena cava wall. Penetration of

the legs into the vena cava wall will occur in the case of the Denali, although it is probable that the rate at which that occurs over time for a given leg will be slower than in the absence of a penetration limiter. Filters are often implanted in patients for a substantial period of time, and therefore it is probable that the Denali will be implanted in any given patient for long enough for some penetration of the leg into the vena cava to occur.

I have shown in my assessment of Bard filters, as stated in my opinions during deposition, that penetration and perforation contributes to tilting, and tilting contributes to penetration and perforation. Furthermore, there is evidence from the behavior of the Meridian filter as described above that the caudal anchors on its limbs were unable to inhibit tilt. In addition, the caudal migration tests of the Denali filter carried out by Bard [46] did not prove that caudal migration of its feet was impossible *in vivo* after implantation, as noted above. Therefore, it is probable that the caudal anchors on the Denali do not inhibit its tilting. Thus there is a likelihood for tilt to occur in the Denali after implantation, and this will, in turn, make it probable that the limbs of the Denali filter will penetrate and perforate the wall of the vena cava. This penetration and perforation of the walls of the vena cava by the limbs of the Denali filter will then enhance the probability of further tilting of the device. Together, the tilting and penetration of the vena cava walls will increase the probability of fatigue fracture of the limbs of the Denali filter (see BPV-17-01-00170625 at 170633 [50]).

As the material of the Denali is the same as that of the Eclipse and the Meridian, *i.e.* electropolished nitinol, endothelialization of the Denali will occur in a manner similar to that which occurs for these other Bard models.

In view of my assessment of the design features of the Denali filter I conclude that it will have problems similar to those of the other Bard filters, as the Denali will penetrate the wall of the vena cava, and tilt, albeit at somewhat slower rates than in the other filters. I note that Bard acknowledged the fact that it is very similar in design to the previous Bard models, among them the Recovery, G2, G2 Express, Eclipse and the Meridian, and therefore in performance and in terms of potential adverse events. [redacted] The Denali filter will also experience endothelialization by the tissue of the vena cava wall. As all of those phenomena of penetration, tilt and endothelialization contribute to fatigue fracture, it is probable that the Denali filter will also experience fatigue fractures after implantation. Therefore, in my opinion, the Denali will suffer adverse events almost as much as is experienced in the previous Bard models of IVC filters. In addition, Bard did not demonstrate that fatigue fracture would not occur after implantation even in the absence of penetration, tilt and endothelialization. Therefore, it is possible that the Denali filter can experience fatigue fracture even if it does not tilt, penetrate the wall of the vena cava or endothelialize.

I note that my assessment indicates that Bard failed to follow best practices, standard industry procedures and adherence to diligence in choosing to re-design their IVC filter as the Denali without first establishing the root causes for the deficiencies and problems suffered by the G2, G2 Express, Eclipse and Meridian filters. Therefore, this episode represents a violation by Bard of engineering professional and industry standards. In the absence of knowledge of the root

cause of the deficiencies and problems of the G2, G2 Express, Eclipse and Meridian filters, Bard was unable to select a design change that would actually deal with those deficiencies and problems. The features of the G2, G2 Express, Eclipse and Meridian filters that I have just described are deficiencies of their designs. These design deficiencies are the result of Bard's failure to adhere to professional and industry standards in the engineering activities involved in the conceptualization, design and analysis of those filters and the Denali model. For example, the attempts to identify all possible failure modes of the Denali filter were inadequate, and the Denali model was not thoroughly tested prior to being marketed. In addition, the fact that the Denali filter was placed on the market despite knowledge by Bard and its employees of the many failures experienced by filters that were quite similar is contrary to engineering professional, industry and government standards, which require design modifications to eliminate potential causes of failures when failure modes are discovered. In addition, it is clear that Bard did not use design and analysis methods that conformed to the state of the art in its industry at the time the Denali filter was designed. Proper design and analysis methods would have identified the potential failure modes. For example, I have seen no evidence that Bard carried out any strain and stress analysis of the Denali filter by the finite element method or by any analytical technique. This includes seeing no evidence that Bard even used strain-analytical methods that were within the skill set of an undergraduate engineering student, and which would have shown Bard that the Denali design had potential failure mechanisms that would probably compromise it after implantation in patients. Furthermore, Bard's conduct in designing the Meridian filter was contrary to GHTF Essential Principles of Safety and Performance 1 through 4 & 6 as listed above. Bard also failed to adhere to the additional bulleted GHTF essential principle stated above relevant to protection of the patient from mechanical risks. As all of these GHTF essential principles are accepted as authoritative industry standards, this shows that Bard was failing to adhere to the relevant industry standards when it designed the Bard Denali filter. I note that the conceptualization, design, analysis and bench testing of the Denali filter predated the publication of the GHTF essential principles; however, these essential principles enunciated by GHTF codify the industry and professional standards that had prevailed for some time prior to the time when the Denali filter was developed. Therefore, these essential principles represent standards that Bard should have adhered to when it conceptualized, designed, analyzed and bench tested the Denali filter. I note that in my reports such as [21] I have extensively described why Bard's design procedures used for the Recovery and G2 filters were deficient and how they failed to meet accepted objective standards. These same criticisms apply also to the manner in which Bard carried out the design of the Denali model; my reports should be consulted to obtain more complete details. In addition, Bard was not frank and honest with the FDA in that the company did not fully inform the FDA of the deficiencies that the G2 and Eclipse families of filters were exhibiting after implant which could also potentially affect the re-designed Denali model. Thus Bard was not adhering to professional, industry and government standards; these aspects of Bards activities have been documented by Parisian [18], where further details are to be found.

8. **Effect of Fracture**

I note that fracture of limbs of filters can lead to the broken piece migrating elsewhere, such as to the heart or the lungs. In addition, fracture, through removing legs or arms or both, will make the remaining body of the filter more prone to tilt as it will be asymmetric, and the loss of legs, and arms in some cases, will make migration of the remaining body of the filter more probable as it will be less firmly attached to the vena cava wall. It is also possible that the asymmetry of the

remaining filter body after fracture will lead to force distributions on the wall of the vena cava that will accelerate the rate at which one or more of the limbs penetrates and perforates the vena cava wall. This point applies to all filters considered in this report.

9. Biostatisticical Assessment of Bard IVC Filters

I also have reviewed an analysis of adverse event reporting for the various Bard IVC filters [52]. This analysis was performed by a biostatistician, Dr. Rebecca Betensky, and was based on Bard's own internal adverse event data. Dr. Betensky's analysis [52] shows statistically significant differences between the Recovery and the Simon Nitinol Filter (SNF), the G2 and the SNF, the Eclipse and the SNF, the Meridian and the SNF, and the Denali and the SNF. Dr. Betensky's analysis [52] also shows that all Bard filters, including the Eclipse, Meridian, and Denali, had higher rates of fracture than the SNF and that those higher rates of fracture are statistically significant in comparison with the SNF fracture rates. The data for the Denali appears to be limited, which is likely due to its lesser time on the market as compared to the earlier generations Bard filters. This adverse event analysis carried out by Dr. Betensky [52] is consistent with and supportive of my opinions in this report.

10. Bard and other Documents Reviewed

As well as numerous documents read and reviewed by me in the preparation of my reports such as [21], and in preparation for my depositions, lists of which documents in all cases I have already provided, I consulted, read and reviewed, or had already read, references [2] and [4-69] and I read and reviewed the relevant sections of references [1] and [3].

Submitted February 3rd, 2017

R McMeeking

Robert M. McMeeking

References

[1] G.E. Dieter and L.C. Schmidt, *Engineering Design* 5th Edition, McGraw-Hill, New York, 2013. See Chapter 18: Legal and Ethical Issues in Engineering Design.

[2] American Society of Mechanical Engineers Code of Ethics for Engineers, https://www.asme.org/about-asme/advocacy-government-relations/ethics-in-engineering

[3] American Society of Mechanical Engineers Codes and Standards, https://www.asme.org/about-asme/standards

[4] International Organization for Standardization (ISO) (home page), http://www.iso.org/iso/home.html

[5] International Medical Device Regulators Forum (IMDRF), (home page) http://www.imdrf.org

[6] GHTF Final Document: GHTF Roles and Responsibilities, GHTF/SC/N2R12:2010, 21st April 2010.

[7] GHTF Final Document: GHTF Guiding Principles, GHTF/SC/N1R8:2005, 20th May 2005.

[8] GHTF Final Document: GHTF Operating Procedures, GHTF/SC/N3R11:2010, 4th November 2010.

[9] GHTF Final Document: GHTF Essential Principles of Safety and Performance of Medical Devices, GHTF/SG1/N68:2012, 2nd November 2012.

[10] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820 Quality System Regulation

[11] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820, Section 820.5 Quality System

[12] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820, Section 820.20 Management Responsibility

[13] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820, Section 820.22 Quality Audit

[14] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820, Section 820.25 Personnel

[15] Code of Federal Regulations (CFR) Title 21, Volume 8, Part 820, Section 820.30 Design Controls

[16] Engineering drawing of the Bard G2 IVC Filter from BPV-15-01-00013398

[17] Engineering drawing of the Bard G2 Express IVC Filter from BPVEFILTER-02-00129929

[18] S. Parisian, *Expert Report: Susan Fox v. C.R. Bard, Inc.*, June 15, 2015.

[19] R.O. Ritchie, *Assessment of the Bard Recovery IVC Recovery Filter Failures: Rachel M. Robles v. Bard Peripheral Vascular, Inc., U.S. District Court for Northern District of Texas, Lubbock, Texas*, December 18, 2014.

[20] A.A. Fasching, *Analysis of Bard IVC G2 Filters*, Report 5004.5507L, Anamet Inc., April 10, 2014.

[21] R.M. McMeeking and M.R. Begley, *Mechanical Reliability of Assessment of the Bard G2 Filter: Susan Fox vs. C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.*, June, 2015.

[22] E.H. Murphy, E.D. Johnson and F.R. Arko, "Evaluation of Wall Motion and Dynamic Geometry of the Inferior Vena Cava Using Intravascular Ultrasound: Implications for Future Device Design," *Journal of Endovascular Therapy* Vol. 15, pp. 349-355 (2008).

[23] S.W. Robertson, A.R. Pelton and R.O. Ritchie, "Mechanical Fatigue and Fracture of Nitinol," *International Materials Review* Vol. 57, Issue 1, pp. 1-36 (2012).

[24] A. Laborda, S. Sierre, M. Malvè, I. De Blas, I. Ioakeim and W.T. Kuo, "Influence of Breathing Movements and Valsalva Maneuver on Vena Caval Dynamics," *World Journal of Radiology* Vol. 6, Issue 10, pp. 833-839 (2014).

[25] Engineering drawing of the Bard G2 Express IVC Filter Cap from BPV-17-01-00132599

[26] Eclipse – Femoral and Jugular/Subclavian Delivery Kits Special 510(k) Premarket Notification (undated but various dates within are Q3 & Q4, 2009) BPVEFILTER-02-00129815 to BPVEFILTER-02-00129942

[27] Device description pages from [26] BPVEFILTER-02-001129843 & BPVEFILTER-02-001129844

[28] Eclipse – Femoral and Jugular/Subclavian Delivery Kits Special 510(k) Premarket Submission November 23, 2009 BPVEFILTER-02-00042265 to BPVEFILTER-02-00042427

[29] Device description pages from [28] BPVEFILTER-02-00042281 to BPVEFILTER-02-00042283

[30] Rotary Beam Fatigue of Nitinol Wire, Anonymous memo to Design History File, unsigned, November 10, 2008 BPV-17-01-001188406 to BPV-17-01-00188408

[31] Filter – Fracture Analysis (May 2016) BPVEFILTER-01-00303182 to BPVEFILTER-01-00303190

[32] Meridian (Eclipse Anchor) V&V Plan, Project Number 8120, TD-01510, Memorandum from Heather Harmison to Meridian DHF Project, #8120, June 24, 2010, BPV-17-01-00148912 to BPV-17-01-00148915

[33] Illustration of the Bard Meridian Filter from BPV-17-01-00148899

[34] Respiratory Flat Plate Fatigue and Corrosion Examination of the Meridian Filter, TP-10-06-02, Brian Boyle, signature page with dates in July 2010, BPV-17-01-00149498 to BPV-17-01-00149522

[35] Diaphragmatic Flat Plate Fatigue and Corrosion Examination of the Meridian Filter, TP-10-12, Brian Boyle, signature page with dates in July 2010, BPV-17-01-00149624 to BPV-17-01-00149660

[36] DV&V Testing of the Meridian Filter and Jugular Delivery System, TP-10-06-13, Brian Boyle, signature page with dates in August 2010, BPV-17-01-00149661 to BPV-17-01-00149699

[37] DV&V Caudal Migration Testing of Meridian and Optease Filters, TP-10-08-09, Brian Boyle, signature page with dates in August 2010, BPV-17-01-00149835 to BPV-17-01-00149858

[38] Bench Top Tilt Testing of Competitive Filters, TD-01964, Memorandum from Brian Boyle to Design History File, Project #8120, 18th July 2011, BPV-17-01-00149815 to BPV-17-01-00149834

[39] S. Suresh, *Fatigue of Materials* 2nd Edition, Cambridge University Press (1991).

[40] H. Bjarnason, J.W. Yedlicka Jr., D.W. Hunter, W.R. Castaneda-Zuniga and K. Amplatz, "In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters," *Investigative Radiology*, Vol. 29, pp. 817-821 (1994).

[41] Engineering drawing of the Bard Denali filter from BPV-17-00213377

[42] Engineering drawings of the Bard Denali filter (various projections, details and dimensions) from BPV-17-01-00213375 to BPV-17-01-00213386

[43] Flat plate respiratory fatigue and corrosion examination test protocol and report Denali filter, TP-10-06-15, Andrzej Chandusko BPV-17-01-00213489 to BPV-17-01-00213505

[44] Flat plate diaphragmatic fatigue and corrosion examination test protocol and report Denali filter, TP-10-06-14, Andrzej Chandusko BPV-17-01-00213470 to BPV-17-01-00213487

[45] Denali DV&V Test Protocol and Report-Filter Test Only, TP-10-09-04, Andrzej Chandusko BPV-17-01-00213507 to BPV-17-01-00213539

[46] Denali Filter System – Femoral and Jugular/Subclavian Delivery Kit, Traditional 510(k), 8th February 2013 beginning BPV-17-01-00213103 to BPV-17-01-00217321, including Denali Filter System Original IDE Submission 30th December 2010 beginning BPV-17-01-00213191 as an appendix.

[47] Denali Filter System – Femoral and Jugular/Subclavian Delivery Kit, IDE Supplement 5-Reponse to Deficiencies in Conditional Approval Letter Dated March 17, 2011 (G110001/S005), 9th August 2011 beginning BPV-17-01-00215019

[48] Design History File, Project # 8108, Denali, Pre Market Release Design Review BPV-17-01-00208699 to BPV-17-01-00209456

[49] Design History File, Project # 8108, Denali, Pre Market Release Design Review BPV-17-01-00210084 to BPV-17-01-00211028

[50] Filter – Fracture Analysis (January 2013) BPV-17-01-00170625 to BPV-17-01-00170633

[51] Clinical Evaluation Report CER0014 Rev. 1, Recoverable Vena Cava Filter Systems, Recovery Filter System, G2 X Filter System, Denali Filter System, August 2011, BPVEFILTER-40-00018181 to BPVEFILTER-40-00018246

[52] R. Betensky, Report Description: Statistical analysis of adverse events of Bard IVC Filters, 27th January, 2017.

[53] G2 Express Filter System – Femoral and Jugular/Subclavian Delivery Kits, Special 510(k) Submission, 7th March, 2008 BPV-17-01-00130498 to BPV-17-00130501

[54] G2 Express Filter System – Femoral and Jugular/Subclavian Delivery Kits, Special 510(k) Submission, 12th August, 2008 BPV-17-01-00131320 to BPV-17-00131329

[55] G2 Express Design History File BPV-17-01-00132051 to BPV-17-01-00132648

[56] Summary data to Support ECLIPSE Special 510(k) Submission, 25th November 2009, BPVEFILTER-08-00024913 to BPVEFILTER-08-00024920

[57] Eclipse Filter System – Femoral and Jugular/Subclavian Delivery Kits, Special 510(k) Submission 23rd November, 2009 BPVEFILTER-02-00042265 to BPVEFILTER-02-00042427

[58] Eclipse – Femoral and Jugular/Subclavian Delivery Kits Special 510(k) Premarket Notification BPVEFILTER-02-00129815 to BPVEFILTER-02-00129942

[59] Eclipse Filter System – Femoral and Jugular/Subclavian Delivery Kits, Response to FDA Questions, 17th December, 2009 BPVE-01-00867137 to BPVE-01-00867144

[60] Eclipse Filter System - Femoral and Jugular/Subclavian Delivery Kits, 510(k) Summary and Clearance BPVEFILTER-01-00568455 to BPVEFILTER-01-00568460

[61] Appendix 2. 510(k) Summary Eclipse Filter System BPVEFILTER-02-00026538 to BPVEFILTER-02-00026541

[62] Design History File – Qualification Phase – Eclipse BPV-17-01-00108342 to BPV-17-01-00108730

[63] Vail (Eclipse) Design History and Transfer Documents (Including Sections of Corporate Quality Assurance Manual) BPV-17-01-00145634 to BPV-17-01-00146075

[64] Meridian DHF Project #8120 Binder 1 of 5 BPV-17-01-00148661 to BPV-17-01-00149126

[65] Meridian DHF Project #8120 Binder 2 of 5 BPV-17-01-00149127 to BPV-17-01-00149522

[66] Meridian DHF Project #8120 Binder 3 of 5 BPV-17-01-00149523 to BPV-17-01-00149903

[67] Meridian DHF Project #8120 Binder 4 of 5 BPV-17-01-00149904 to BPV-17-01-00150189

[68] Meridian DHF Project #8120 Binder 5 of 5 BPV-17-01-00150190 to BPV-17-01-00151046

[69] Deposition of Michael Adam Randall, In Re: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION) MD No.: 02641, 18th January, 2017.

Figure Captions

Figure 1. Engineering drawing of the Bard G2 IVC Filter

Figure 2. Engineering drawing of the Bard G2 Express IVC Filter

Figure 3. Engineering drawing of the Bard G2 Express IVC Filter Cap

Figure 4. Illustration of the Bard Meridian IVC Filter.

Figure 5. Engineering drawing of the Bard Denali IVC Filter

Figure 6. Engineering drawing detail of the cap and retrieval hook of the Bard Denali IVC Filter showing the notches between adjacent limbs of the filter.

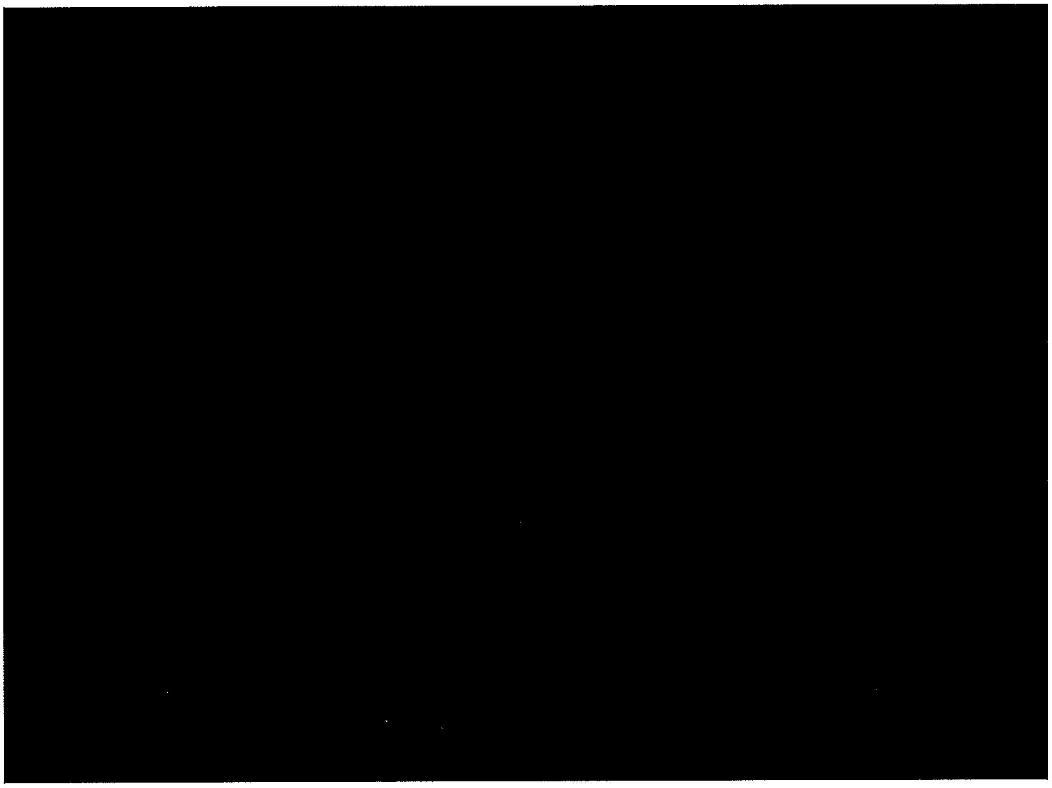


Figure 1: Engineering Drawing of the Bard G2 IVC Filter

[redacted]

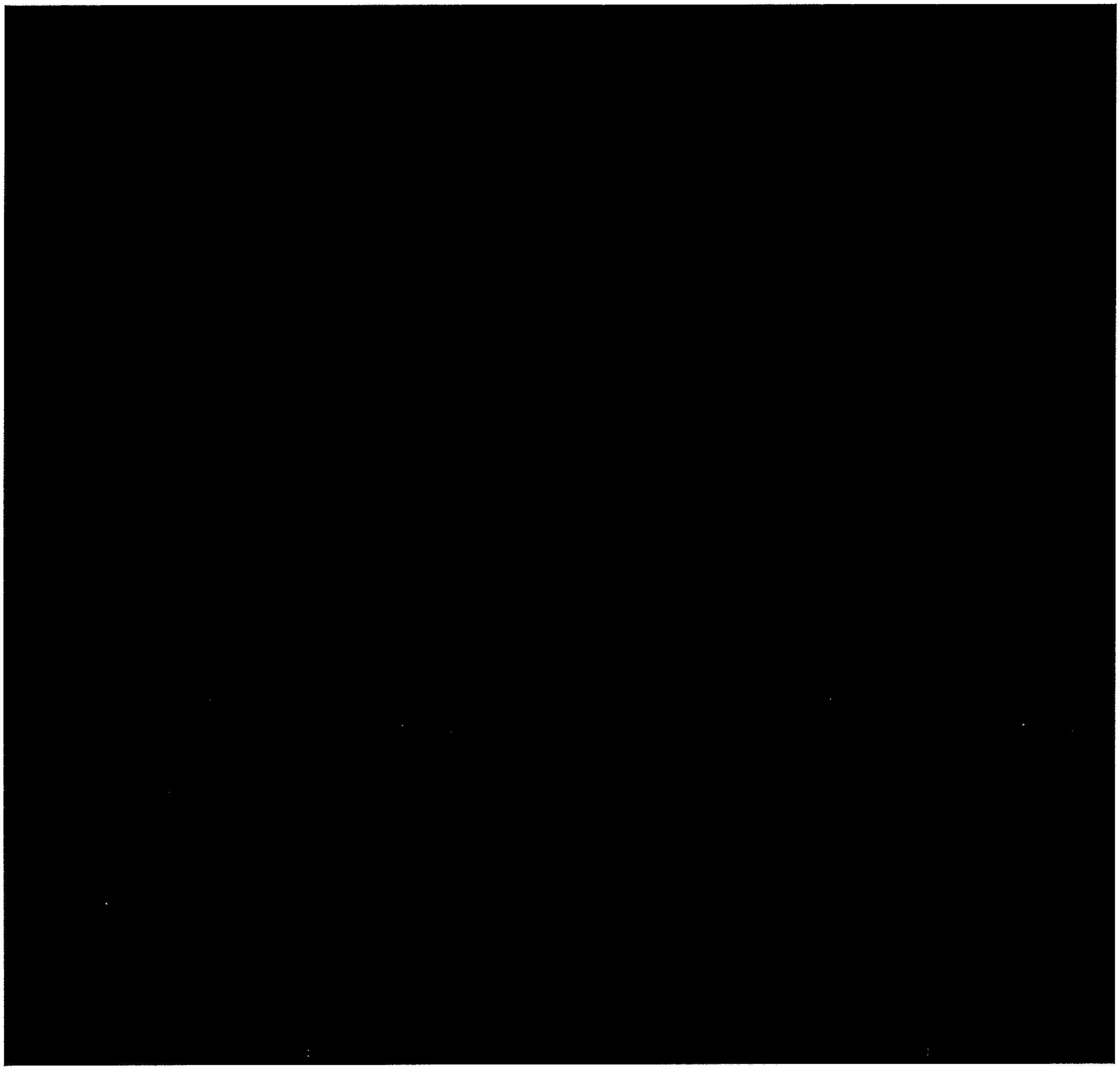
TRADE SECRET/CONFIDENTIAL INFORMATION
Notify CR Bard Before Releasing the Document

BARD

Figure 2: Engineering Drawing of the Bard G2 Express IVC Filter

[redacted]

Figure 3: Engineering drawing of the Bard G2 Express IVC Filter Cap



CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

BPV-17-01-00148899
LMD1

Figure 4: Illustration of the Bard Meridian IVC Filter.

[redacted]

Figure 5: Engineering drawing of the Bard Denali IVC Filter

[redacted]

Figure 6: Engineering drawing detail of the cap and retrieval hook of the Bard Denali IVC Filter showing the notches between adjacent limbs of the filter.